

REMARKS

Applicants submit this Amendment in reply to the Office Action mailed April 11, 2006.

By this Amendment, Applicants cancel claims 32, 42, and 52, without prejudice or disclaimer, amend independent claims 16, 22, and 24 to include the subject matter of respective dependent claims 32, 42, and 52, and also amend independent claim 24 to correct an inadvertent typographical error.

Before entry of this Amendment, claims 16-25 and 31-64 were pending in this application, with claims 17, 23, and 25 having been withdrawn from consideration. After entry of this Amendment, claims 16-25, 31, 33-41, 43-51, and 53-64 are pending in this application, with claims 17, 23, and 25 still withdrawn from consideration. Claims 16, 22, and 24 are the sole examined independent claims.

I. **Section 102(b) Claim Rejections Based on Lazarus**

On pages 2-4 of the Office Action, claims 16, 18-21, 24, 31, 32, 34, 36, 38, 39, 51, 52, 54, 56-62, and 64 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,787,899 to Lazarus. Applicants respectfully traverse this rejection.

Independent claims 16 and 24 have been rewritten to include the subject matter of respective dependent claims 32 and 52. Lazarus does not disclose the claimed invention. For example, as-amended independent claim 16 recites a conduit "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" and "is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole." In another example, as-amended independent claim 24 recites a conduit with a tubular

element "configured to be positioned in the wall of a patient's heart," "wherein the conduit is sufficiently rigid such that the blood flow path remains open during both systole and diastole." Lazarus does not disclose at least these respective aspects of as-amended independent claims 16 and 24 either alone or in combination with the other respective aspects of independent claims 16 and 24.

A. The Claim Recitations Must Receive Patentable Weight

Page 3 of the Office Action recites the following:

The language "for use in a wall of a heart" and "adapted to positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the "bypass conduit" and does not, in itself serve to further limit the structure of the conduit.

Applicants respectfully disagree. First of all, independent claims 16 and 24 do recite structural features, namely, independent claim 16 recites a conduit "adapted to be positioned" and independent claim 24 recites a tubular element "configured to be positioned," and thus are not simply intended use or functional aspects. See, e.g., *In re Venezia*, 189 U.S.P.Q. 149, 151-152 (CCPA 1976) ("Each sleeve of said pair adapted to be fitted over the insulating jacket of one of said cables," "adapted to be affixed," and "adapted to be positioned" are structural limitations.); *R.A.C.C. Industries Inc. v. Stun-Tech Inc.*, 49 U.S.P.Q.2d 1793 (Fed. Cir. 1998) ("A belt of sufficient length to fasten around the torso" is a structural limitation.). In particular, in *In re Venezia*, the court found "nothing wrong in defining the structures of the components... in terms of... the attributes they must possess,..." *In re Venezia*, 189 U.S.P.Q. 149 at 152.

However, even assuming that these recitations are functional language, they must be given patentable weight. As set forth in M.P.E.P. § 2173.05(g):

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. In re Swinehart, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).

A functional limitation must be evaluated and considered, just like any other limitations of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient, or step.

Accordingly, even assuming that the phrase "adapted to be positioned in a heart wall" and "configured to be positioned in the wall of a patient's heart" are functional, such phrases still must be given patentable weight. The allegedly corresponding structure in the prior art must be capable of performing the recited function. While invoking a suitability for a particular function "may render a claim quite broad," as "[b]y its own literal terms a claim employing such language covers any and all embodiments which perform the recited function.... This is not to say, however, that every claim containing 'functional' terminology is broad. Indeed, in many cases it will be obvious that only a very limited group of objects will fall within the intended category." *In re Swinehart*, 439 F.2d at 210 (emphasis removed). In addition, claims 16 and 24 require that the conduit be sufficiently rigid such that the path between the vessel and chamber remains open during both systole and diastole. The Office Action admits that this is a "functional limitation of the claims" (See Office Action at page 4 as relates to claim 32).

Accordingly, the corresponding structure in Lazarus must be capable of being positioned in the heart wall and be sufficiently rigid such that the path between the vessel and chamber remains open during both systole and diastole, as recited in independent claims 16 and 24.

B. Lazarus Does Not Expressly Disclose a Graft Capable of Performing the Claimed Aspects

The Office Action identifies hollow graft 12 as allegedly corresponding to the conduit of independent claims 16 and 24. However, Lazarus expressly discloses hollow graft 12 as being positioned only in blood vessels, and not the heart wall. Similarly, Lazarus does not expressly teach that hollow graft 12 is capable of remaining open during both systole and diastole in a heart wall.

C. Lazarus Does Not Inherently Disclose a Graft Capable of Performing the Claimed Functional Aspect

The Office Action first alleges that “[t]he properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart.” (Office Action at page 3).

In rejecting the subject matter of claim 32 (and 52), which has been incorporated into independent claim 16 (and 24), page 4 of the Office Action then alleges that “the conduit of Lazarus is designed to remain open during both systole and diastole and therefor meets the functional limitation of the claim.” As the Office Action does not show where Lazarus expressly discloses these aspects, the Office Action appears to rely on inherency principles.

The fact, however, that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.

In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.'" *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed Cir. 1999) (citations omitted) (emphasis added).

The Office Action does not cite any evidence to support that hollow graft 12 in Lazarus is necessarily capable of being positioned in a heart wall and sufficiently rigid to remain open during both systole and diastole. Indeed, a conduit so configured may differ from a hollow graft 12 configured to be disposed in a blood vessel for many reasons.

For example, a conduit positioned in a heart wall may experience stresses significantly different than those typically experienced in blood vessels as disclosed in Lazarus. Since the contractile forces experienced during a cardiac cycle, especially during systolic contraction of the heart wall, are far different than the pressures experienced in blood vessels, the Lazarus hollow grafts are not necessarily configured to be positioned in the heart wall.

Lazarus specifically discloses that "[p]referably the graft is made of Teflon, nylon, dacron or the like" (col. 2, lines 39-40), and that "[t]he use of a material such as knitted dacron formed with bifolds 50 allows the graft 12 to readily deform both axially 54 and radially 56" (col. 4, lines 9-12). It is certainly not necessarily true that a hollow graft made solely of any of those flexible, deformable materials could remain open in a heart wall during both systole and diastole.

Lazarus also discloses that "the pressure of the lumen fluid, for example blood, forces the graft 12 against the lumen interior surface 112, to hold the graft 12 in place." (Col. 6, lines 58-61). The graft 12 therefore is constructed so that pressures within a blood vessel lumen will hold graft 12 in place. Again, it is certainly not necessarily true, and in fact is rather unlikely, that a hollow graft so configured could remain open in a heart wall during both systole and diastole due to the higher pressure exerted by the heart muscle.

Accordingly, for at least these reasons, Lazarus does not inherently disclose a conduit capable of being positioned in a heart wall and sufficiently rigid to remain open during both systole and diastole, as set forth in independent claims 16 and 24.

Accordingly, for at least these reasons, Applicants respectfully request withdrawal of the Section 102(b) rejection based on Lazarus.

II. Section 103(a) Claim Rejections Based on Lazarus, Robinson, Lee, and Bowen

On pages 4-5 of the Office Action, claims 16, 18-21, 22, 24, 31-36, 38-45, 47-62, and 64 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus in view of U.S. Patent No. 4,604,762 to Robinson ("Robinson") or U.S. Patent No. 5,123,917 to Lee ("Lee"); and claims 37, 46, and 63 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus in view of U.S. Patent No. 2,127,903 to Bowen ("Bowen").

With regard to the rejection of as-amended independent claims 16 and 24 (i.e., the subject matter of former dependent claims 32 and 52) and their respective dependent claims, at least because none of Robinson, Lee, or Bowen are cited as

remedying the aforementioned deficiencies of Lazarus, and indeed, each of Robinson, Lee, and Bowen are cited for allegedly disclosing other aspects set forth in the claims, Applicants respectfully request withdrawal of the Section 103(a) rejections of independent claims 16 and 24 and their respective dependent claims.

With regard to the rejection of independent claim 22, Applicants respectfully traverse because as-amended independent claim 22 recites a conduit "adapted to be positioned in the heart wall between a coronary vessel and a chamber of the heart" and that "is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole." Applicants assume that the Office Action takes the same position with respect to these aspects of as-amended independent claim 22 (i.e., the subject matter of former dependent claim 42) as it took with respect to the similar aspects of as-amended independent claims 16 and 24 (i.e., former dependent claims 32 and 52). Accordingly, Applicants respond to this rejection for the same reasons as set forth above, which are incorporated by reference here.

Accordingly, for at least these reasons, Applicants respectfully request withdrawal of the Section 103(a) rejections of independent claim 22 and its respective dependent claims.

Furthermore, should independent claims 16 and 24 be allowed, Applicants respectfully request rejoinder and allowance of dependent claims 17 and 25, as set forth in M.P.E.P. § 821.04.

Applicants further submit that claims 17-21, 25, 31, 33-41, 43-51, and 53-64 depend either directly or indirectly from one of independent claims 16, 22, and 24, and

are therefore allowable for at least the same reasons that their respective independent claims are allowable. In addition, each of the dependent claims recite a unique combination that is neither taught nor suggested by the cited references and therefore each also is separately patentable.

In view of the foregoing remarks, Applicants request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification and claims in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and
charge any required fees not otherwise provided for to our Deposit Account No.
06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 

Michael W. Kim
Reg. No. 51,880